

specification, they are not specific to the isolated DNA molecule comprising the DNA sequence of SEQ ID NO:1.

The Examiner contends that the utility of the isolated DNA molecule is based on the assertion that it encodes a sequence which has homology to the Wnt binding domain of the extracellular binding domains of the Frizzled/Frazzled family of proteins. The Examiner contends that there is no teaching of which of the more than a dozen Wnt proteins the encoded product of SEQ ID NO:1 would be capable of binding or which receptor binding interactions SDF-5 would be capable of regulating. The Examiner does not recognize the protein encoded by SEQ ID NO:1 as useful for binding Wnt protein.

The Examiner points out that the human SDF-5 expression pattern differs from the murine homologue. The Examiner contends that even if SDF-5 is an SDF-5 protein or a Frizzled/Frazzled protein it cannot be predicted what the protein does. The Examiner states that there is no teaching of a relationship to any specific disease and that to determine "real world use" additional experimentation is required and finally that the specification essentially gives an invitation to experiment.

Applicants assert that the invention is supported by a specific utility or a substantial activity. With respect to lack of utility, the PTO is required to establish a *prima facie* case. In re Brana, 34 U.S.P.Q.2d 1436, 1440-1441 (Fed. Cir. 1995). Under the Utility Examination Guidelines, 66 Fed.Reg.1092(2001); 60Fed. Reg. 36263(1995), the Patent Office bears the burden of *prima facie* proof that no credible utility has been asserted for the claimed invention. As defined in the Guidelines, the PTO is required to "establish that it is more likely than not that a person skilled in the art would not consider

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credible any specific utility asserted by the applicant for the claimed invention (emphasis supplied).” The PTO has failed to meet its burden to establish a *prima facie* case of unpatentability.

Applicants provide the nucleotide sequence of human SDF-5 and the protein encoded, and methods of making human SDF-5 polypeptides using the DNA sequences. In addition, Applicants have provided art-recognized credible uses of SDF-5 including inducing formation/growth differentiation proliferation and/or maintenance of chondrocyte and/or cartilage tissue, but the Examiner contends that this does not provide utility to the claimed invention. In addition the examiner recognizes that the protein encoded by SEQ ID NO:1 may be capable of binding Wnt protein and may be capable of regulating the interaction of Wnt genes to receptor proteins. The asserted utility is based on the fact that the molecule of SEQ ID NO:1 encodes a sequence which has homology to the Wnt binding domain of the extracellular binding domains of the Frizzled/Frazzled family. Thus, the skilled artisan can readily both make and use the SDF-5 proteins of the present invention without undue experimentation.

The Wnt genes are known to play a role during patterning and development of a number of embryonic structures. Receptors for Wnts are members of the Frizzled family of proteins with a cysteine rich domain that binds the Wnt protein. Frazzled shares homology with the extracellular binding domain of Frizzled. As stated in the specification at page 10, line 26 through page 11 line 9, “ it is of particular interest that the human SDF-5 gene appears to encode a secreted factor, thus providing soluble receptors which may be capable of binding with the Wnt proteins, thus initiating and/or blocking signal transduction by the Wnt proteins. Thus, the human SDF-5 gene family

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may be capable of regulating the binding interaction of Wnt genes to receptor proteins, such as the Frizzled receptor proteins. The potential signal transduction regulation activities of these proteins along with the presence and/or expression of Wnt genes in pancreas and other organs suggests that human SDF-5 is an important regulator of differentiation of tissue and organs. Thus, the protein of the invention may be useful in wound healing, tissue and organ repair and regeneration processes as well as in the differentiation of tissue, for example in embryonic development. In particular, it has been observed by the inventors that the human SDF-5 protein may be useful for the induction, formation, growth differentiation proliferation and/or maintenance and repair of chondrocytes and or cartilage tissue.

In providing the nucleotide sequence and recombinant expression system for SDF-5 applicants have provided the skilled artisan with the novel protein. Following Applicants' disclosure of methods of making SDF-5, activity and assays of SDF-5, the artisan can readily determine the in vivo activities of Applicants' disclosed protein without undue experimentation. Thus, Applicants have provided a novel member of a well-recognized class of compounds with known activities the Frazzled family of proteins. It is well known to those skilled in the art that members of this family are capable of activities including inducing formation/growth differentiation proliferation and/or maintenance of chondrocyte and/or cartilage tissue. Thus, there is no question that the skilled artisan would consider Applicants' disclosed utilities of SDF-5 to be specific or substantial.

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## Rejections Under 35 USC § 112

Claims 1-17 remain rejected because the Examiner contends, one skilled in the art, for the reasons set forth in the § 101 rejection described above, would not know how to use the claimed invention. Applicants assert that for the reasons Applicants have set forth above, the claimed invention is supported by a specific utility and therefore one skilled in the art would know how to use the claimed invention

## CONCLUSION

In view of the foregoing remarks, Applicants respectfully request reconsideration and withdrawal of the rejections of record and issuance of the claims as amended. Should the Examiner believe that a telephonic interview would assist in clarifying any remaining issues, or to otherwise expedite prosecution, Applicants respectfully invite the Examiner to call the undersigned attorney at the telephone number provided below.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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